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(54) **STENTS FOR PROSTHETIC HEART VALVES**

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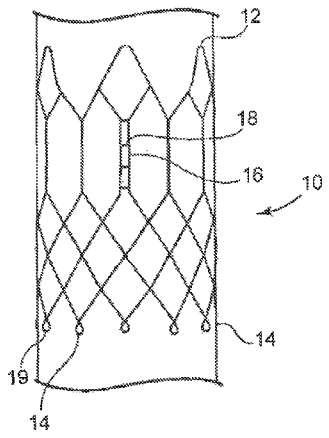
(57) **ABSTRACT**

A stented valve prosthesis for implantation within a native mitral valve having a generally tubular expandable stent structure having a first end, a second end, a central body portion having one or more openings, and a longitudinal axis. A wing portion extends outwardly from the stent structure and away from the longitudinal axis of the stent structure in an expanded deployed configuration. A radius of the wing portion is greater than a radius of the central body portion in the expanded deployed configuration, and the wing portion fits within one of the openings in the central body portion of the stent structure in a crimped delivery configuration. A valve structure having a plurality of leaflets is attached to an interior of the stent structure.

20 Claims, 17 Drawing Sheets



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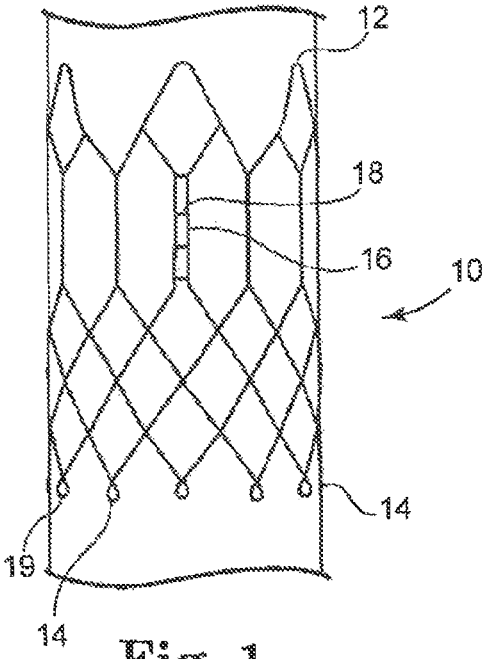

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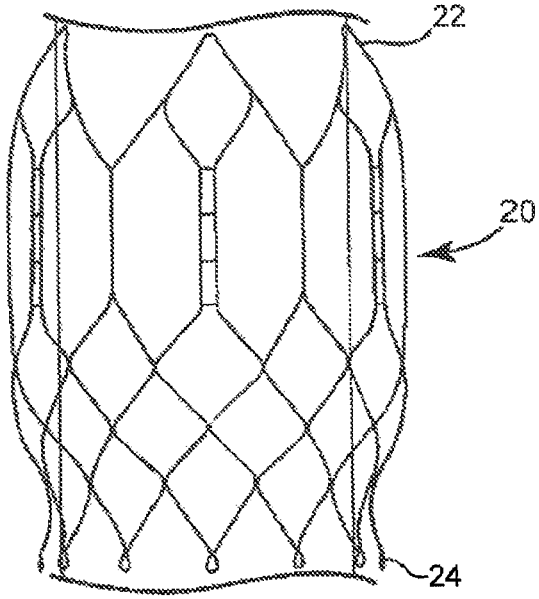

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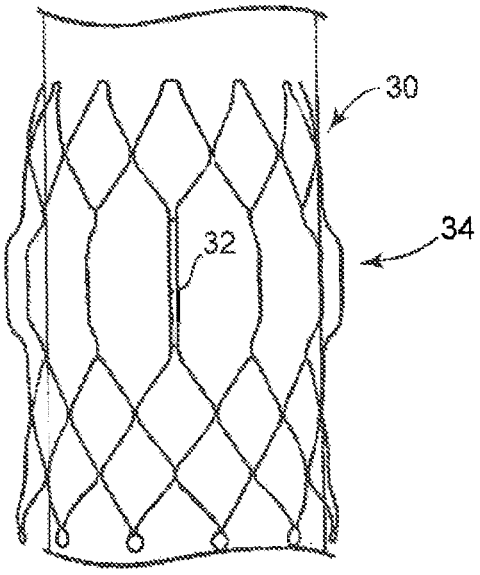

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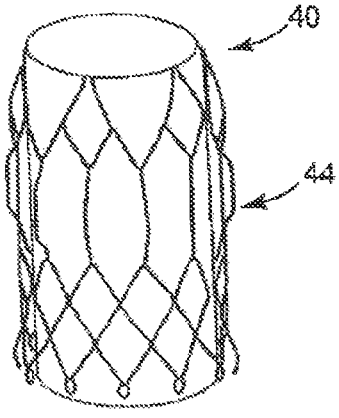

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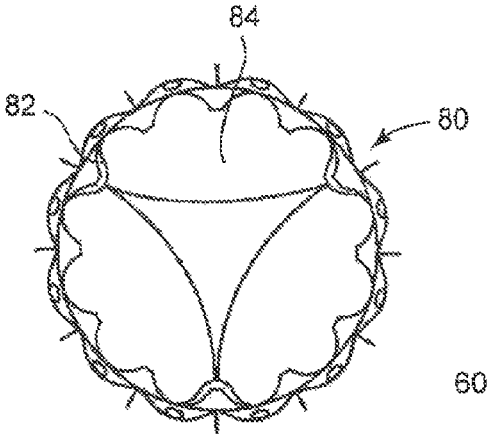

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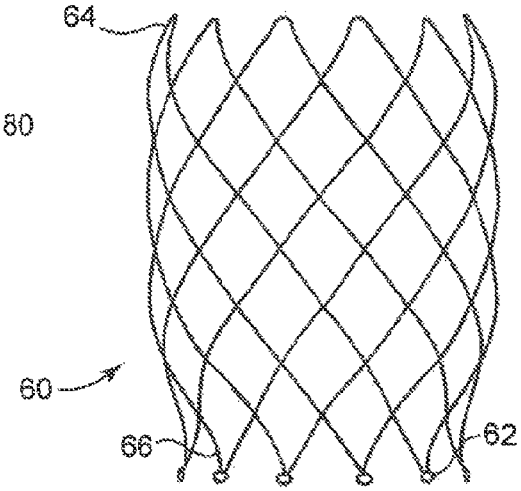

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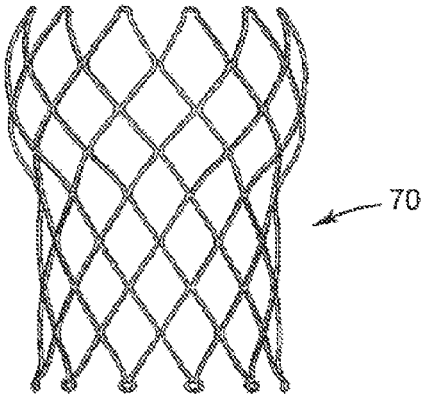

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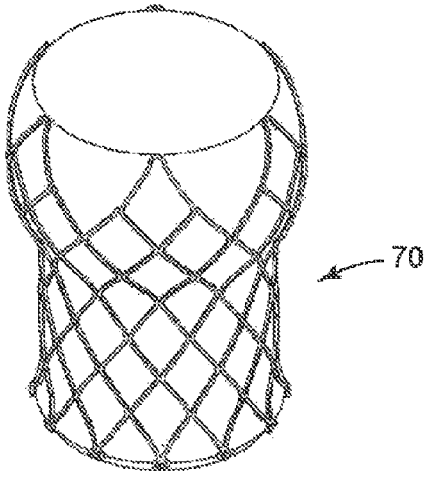

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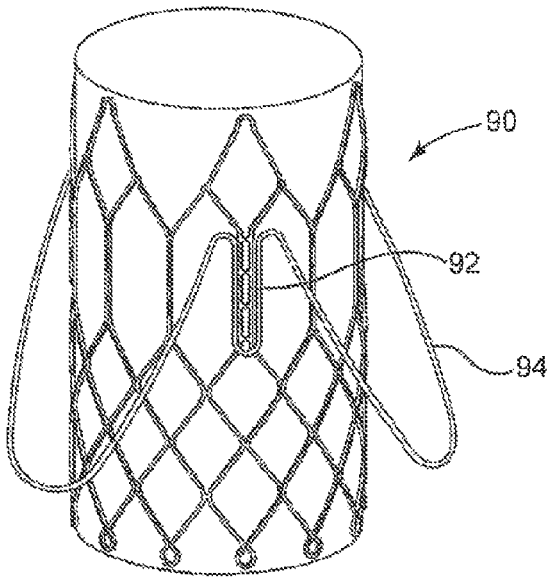

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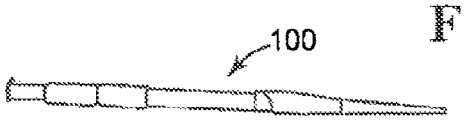

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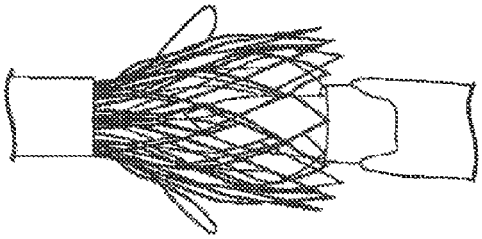

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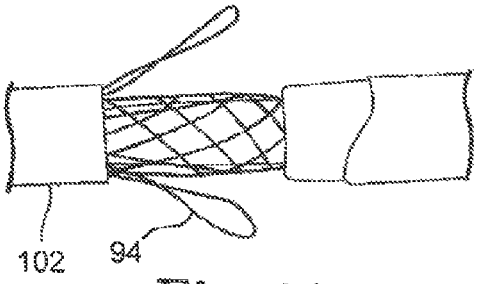

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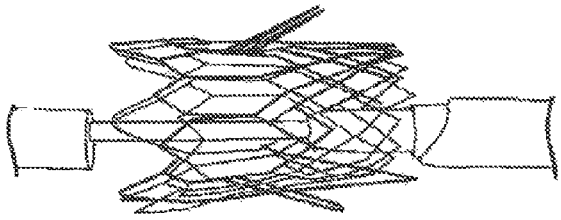

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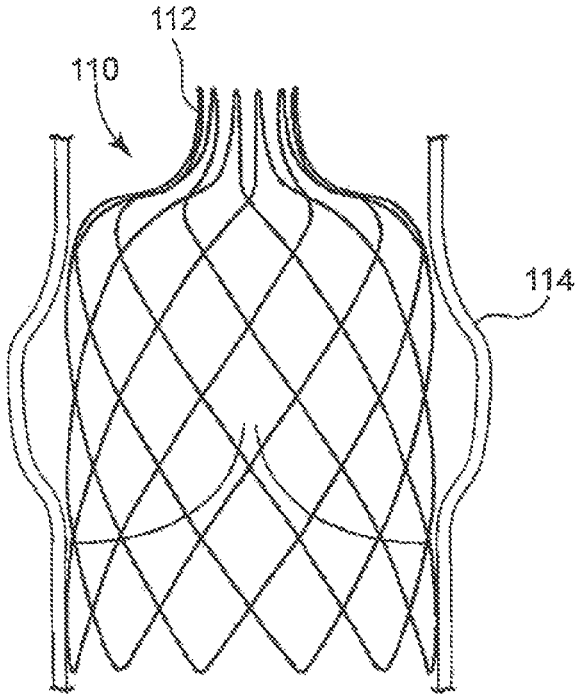

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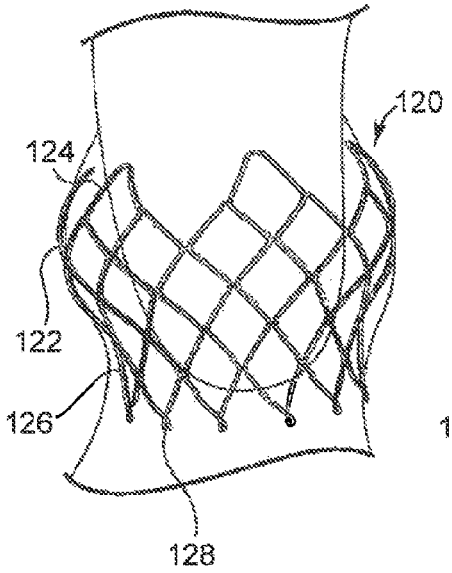

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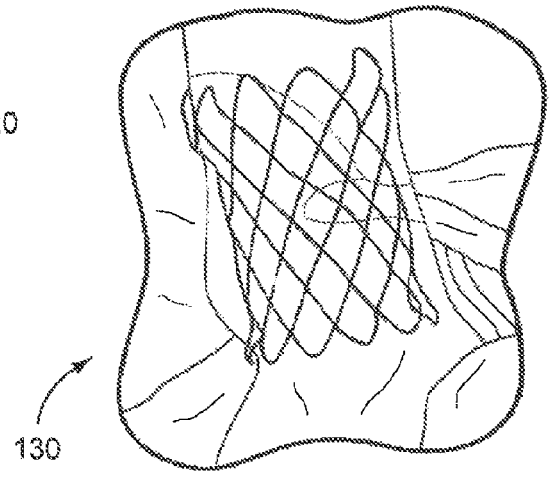

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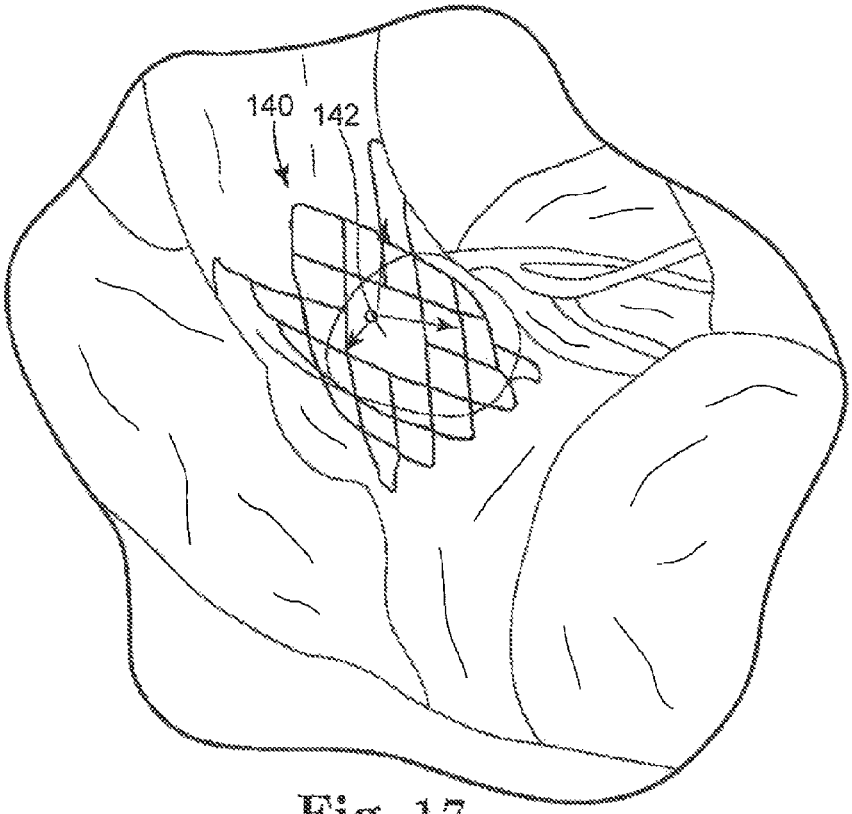

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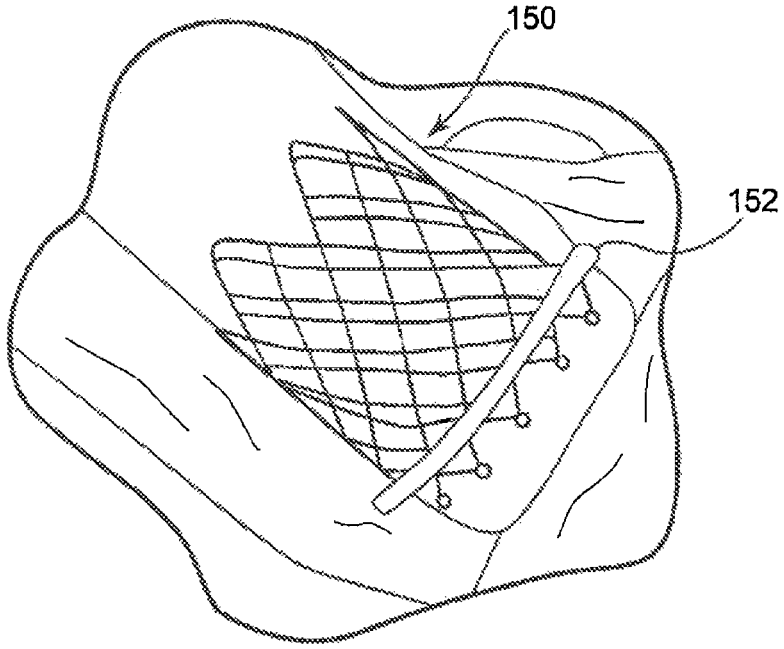

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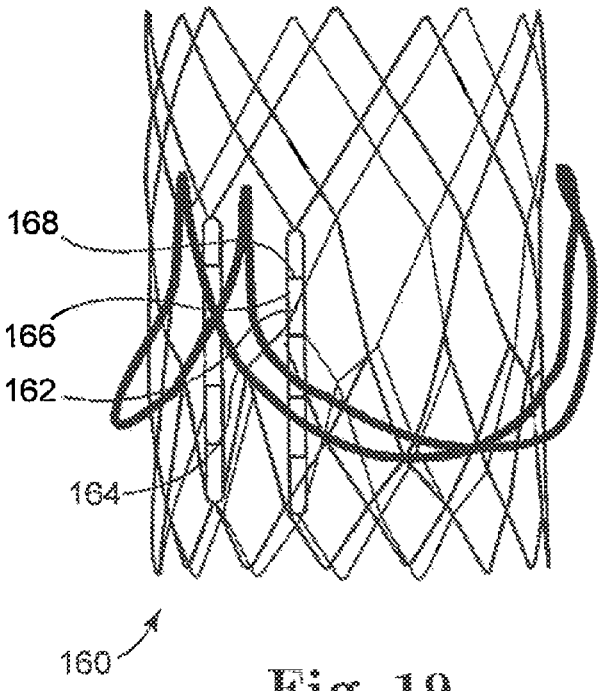

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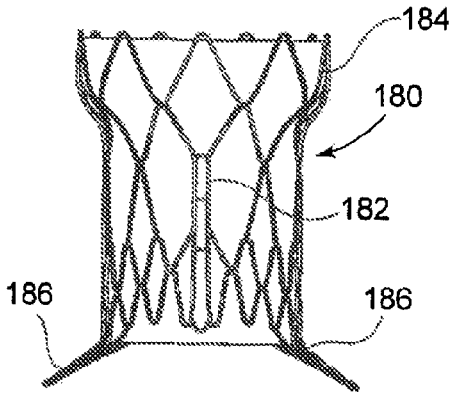

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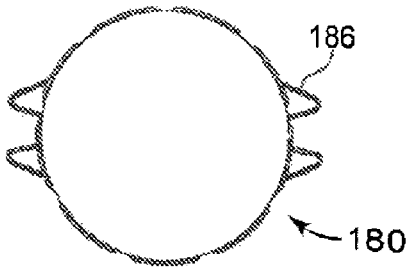

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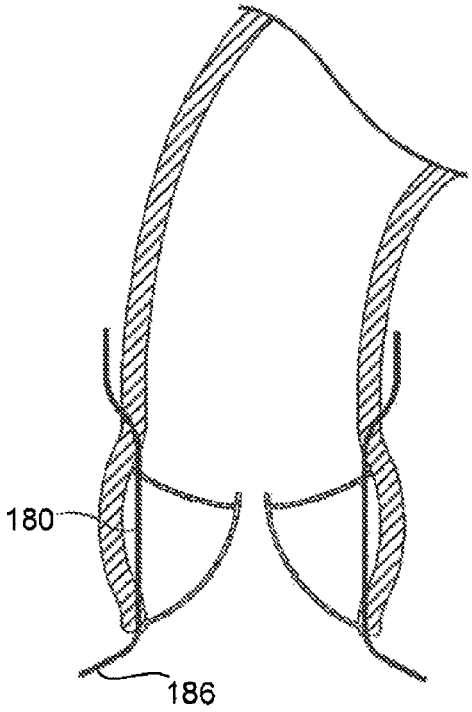

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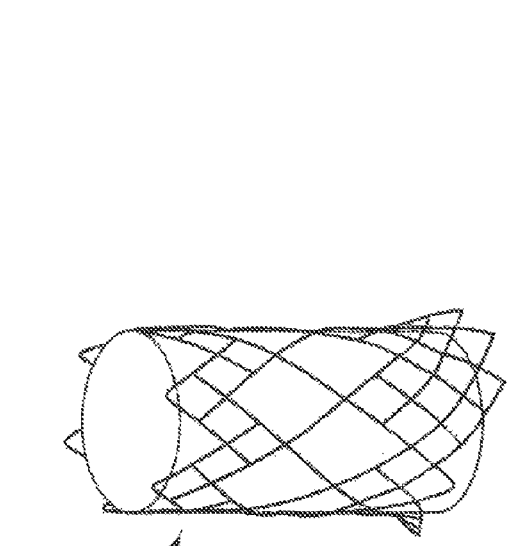

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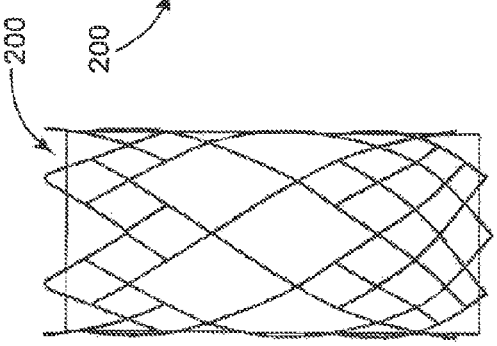

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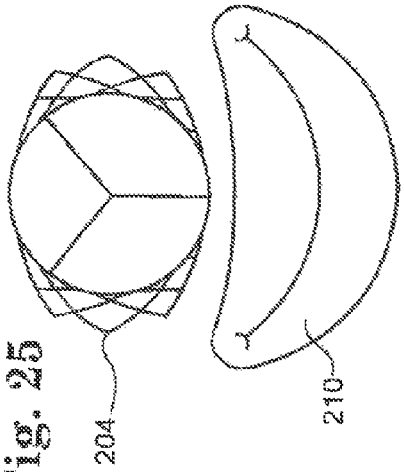

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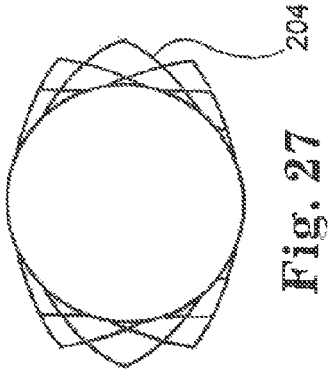

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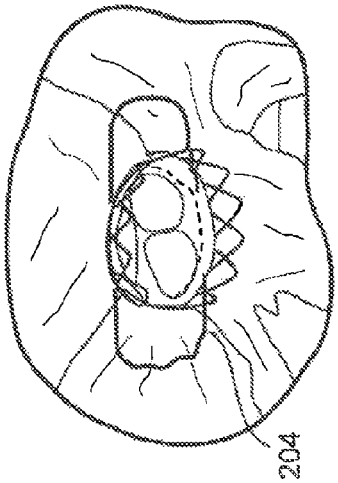

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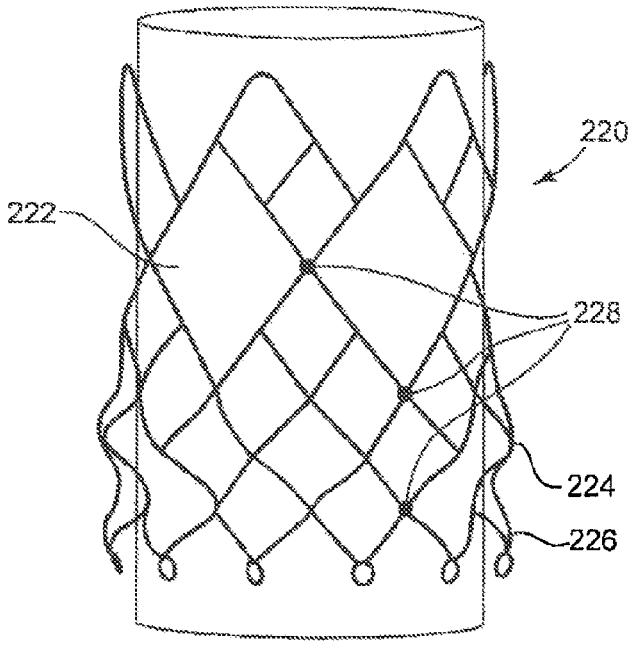

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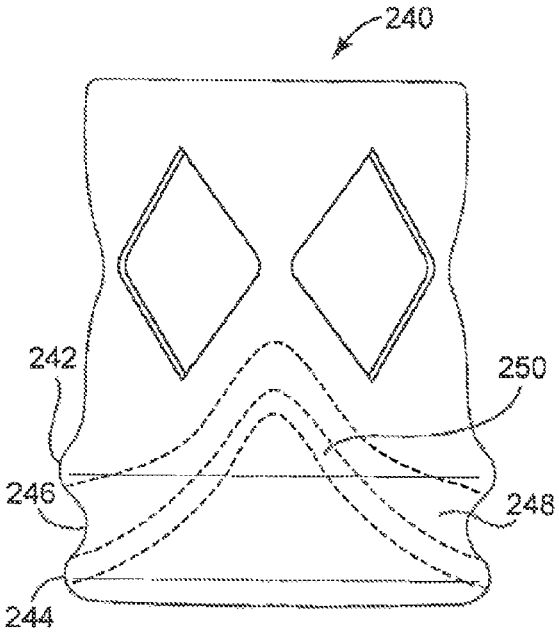

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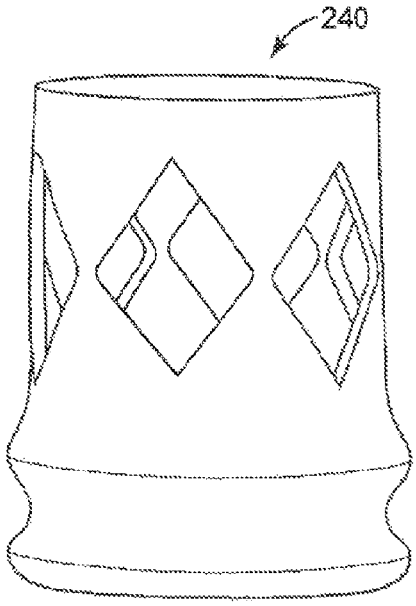

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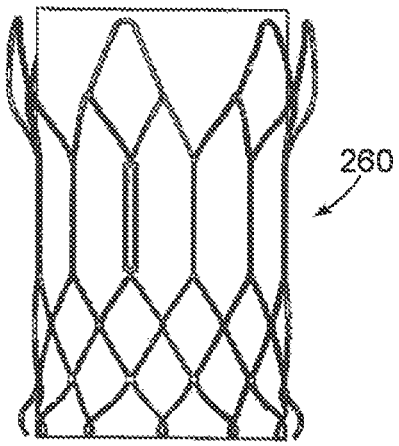

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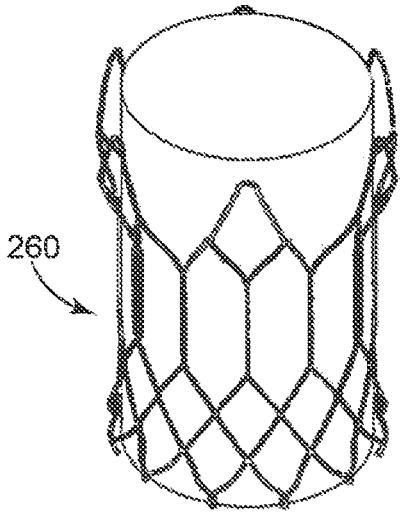

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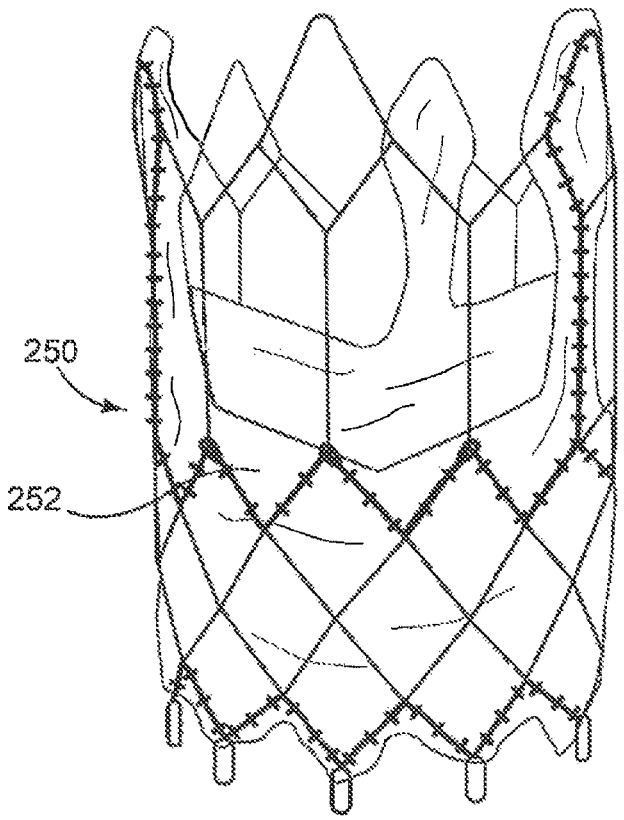

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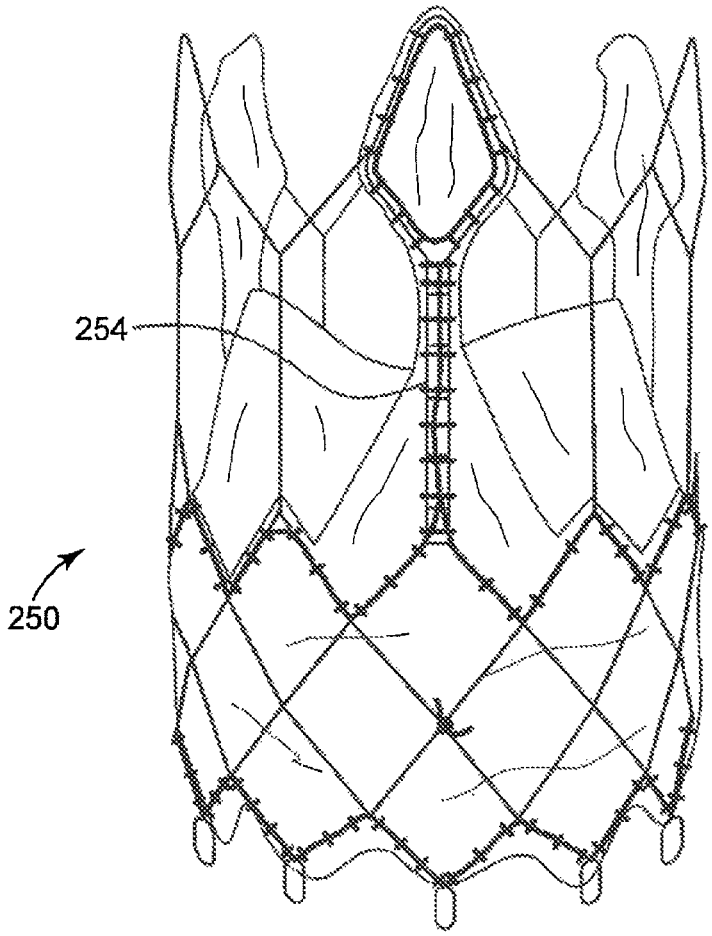

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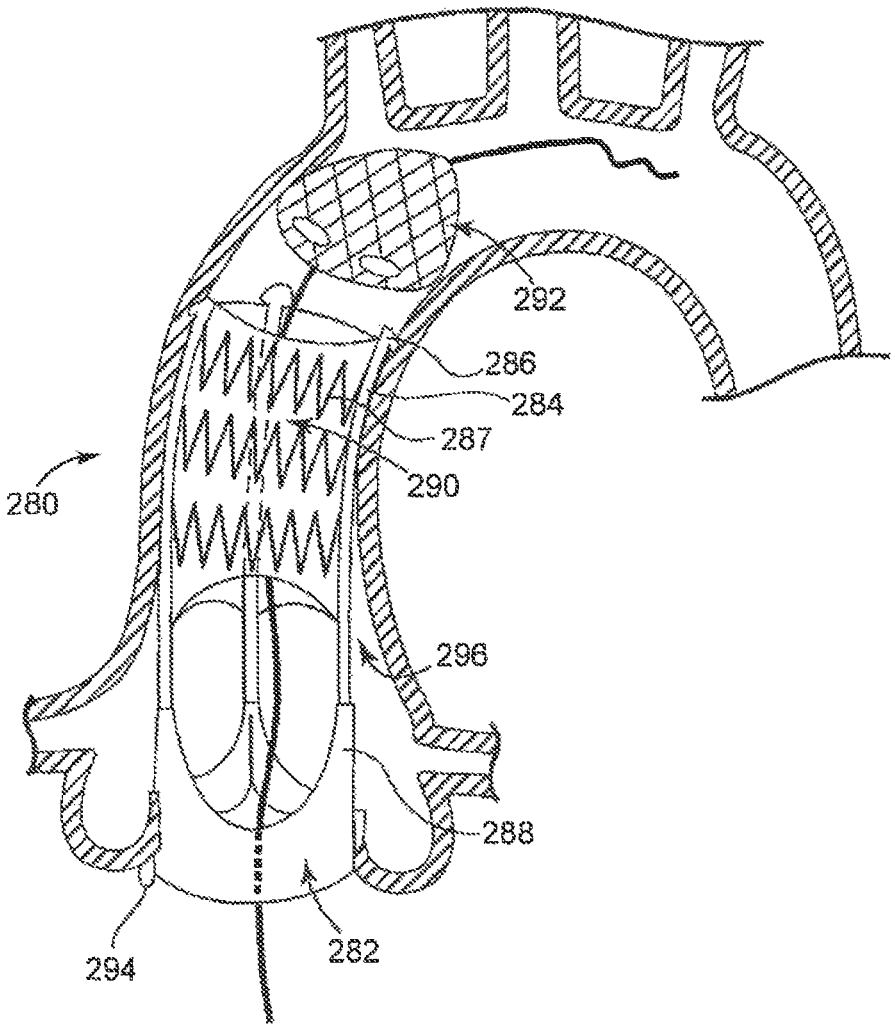

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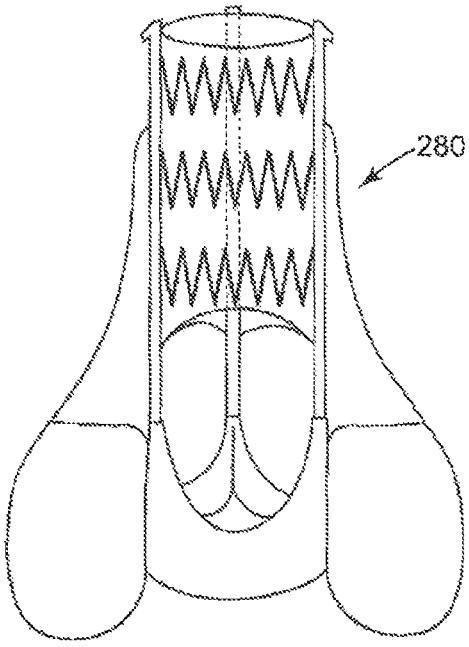

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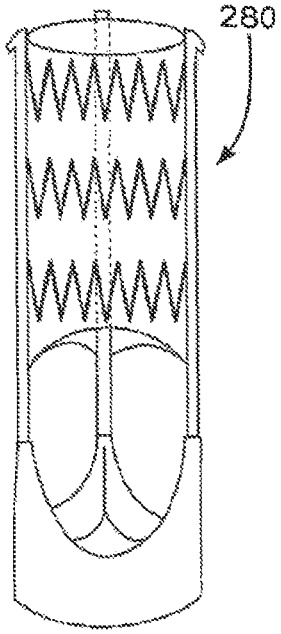

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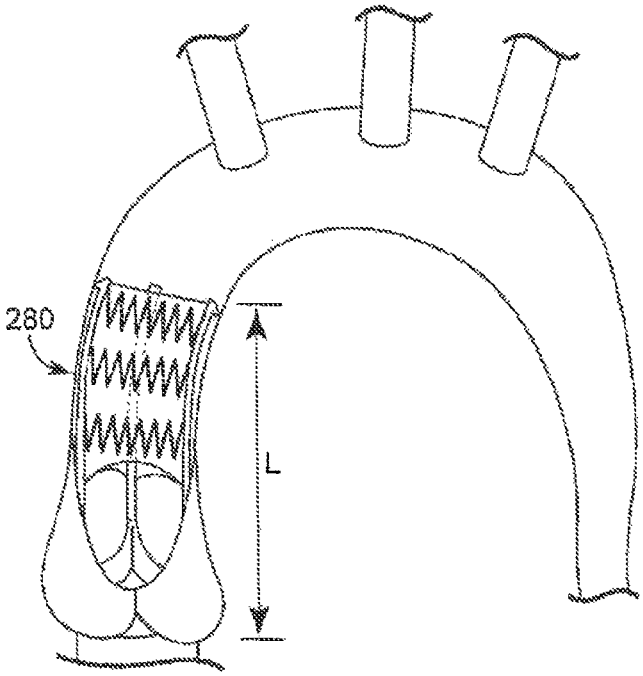

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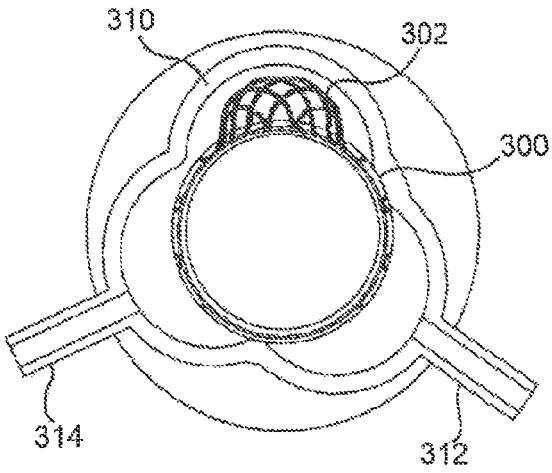

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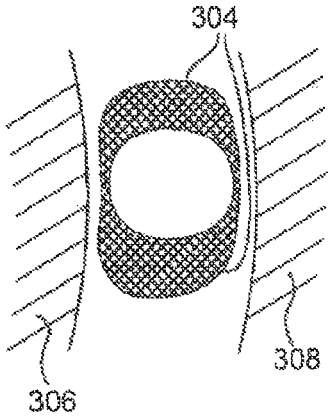

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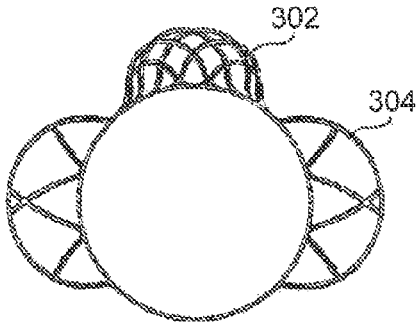

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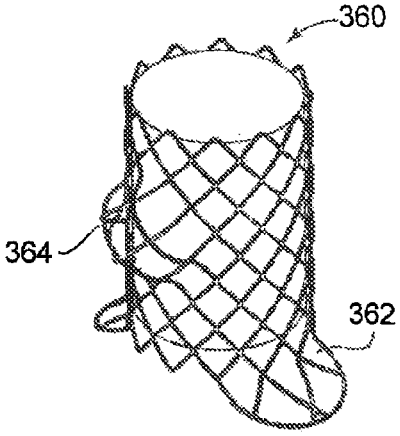

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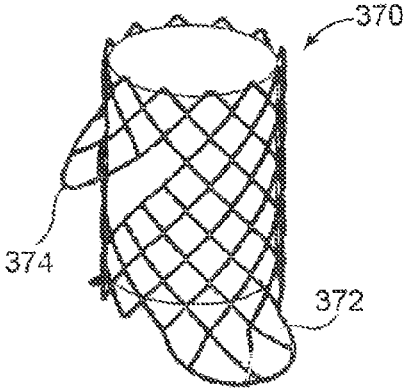

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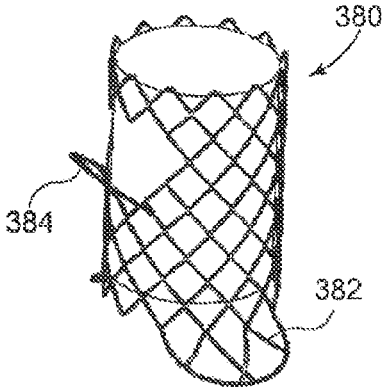

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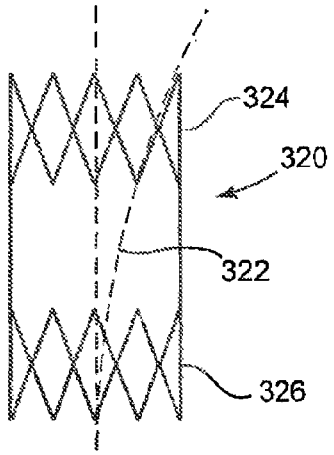

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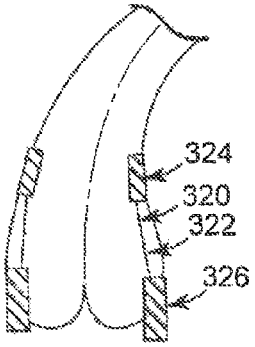

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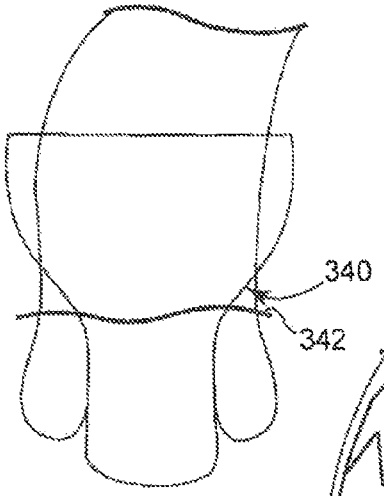

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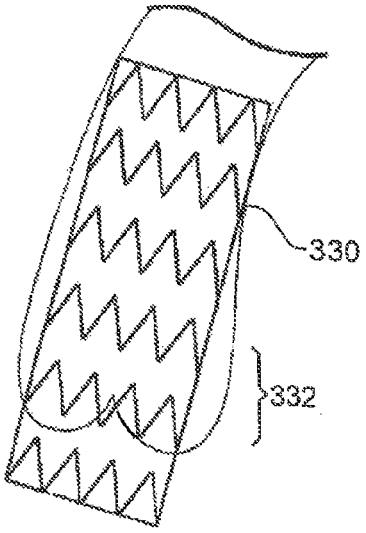

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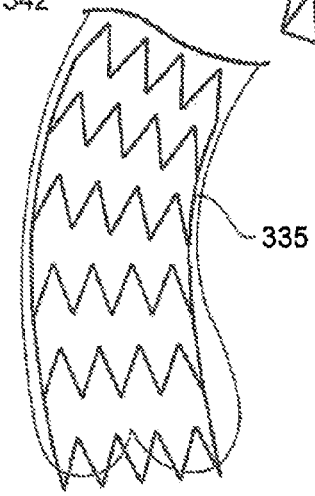

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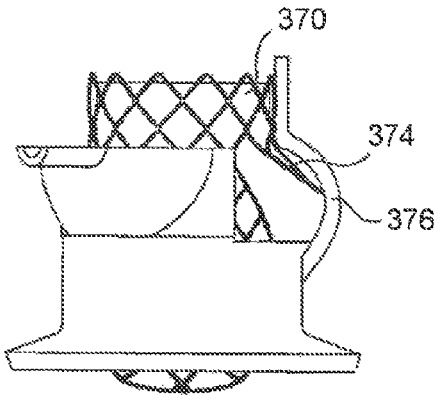

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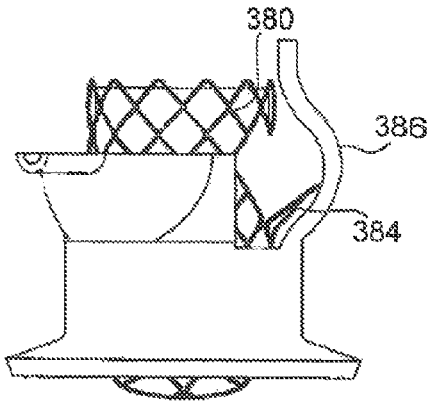

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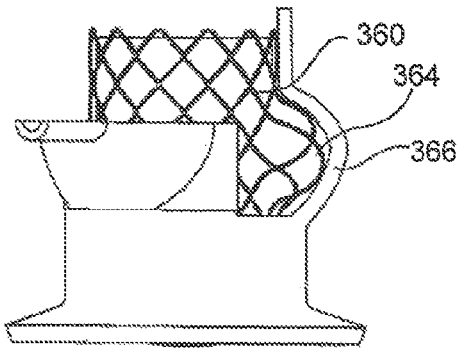

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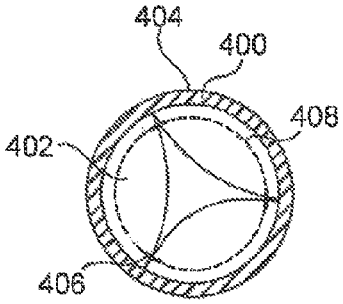

Fig. 54

STENTS FOR PROSTHETIC HEART VALVES

CROSS-REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. application Ser. No. 13/112,656, filed May 20, 2011, which is a continuation of U.S. application Ser. No. 12/321,760, filed Jan. 23, 2009 and titled "Stents For Prosthetic Heart Valves", which claims priority to U.S. Provisional Application Nos. 61/062,207, filed Jan. 24, 2008, and titled "Delivery Systems and Methods of Implantation for Prosthetic Heart Valves"; and 61/075,902, filed Jun. 26, 2008 and titled "Heart Valve"; the entire contents of which are incorporated herein by reference in their entireties.

TECHNICAL HELD

The present invention relates to prosthetic heart valves. More particularly, it relates to devices, methods, and delivery systems for percutaneously implanting prosthetic heart valves.

BACKGROUND

Diseased or otherwise deficient heart valves can be repaired or replaced using a variety of different types of heart valve surgeries. Typical heart valve surgeries involve an open-heart surgical procedure that is conducted under general anesthesia, during which the heart is stopped while blood flow is controlled by a heart-lung bypass machine. This type of valve surgery is highly invasive and exposes the patient to a number of potentially serious risks, such as infection, stroke, renal failure, and adverse effects associated with use of the heart-lung machine, for example.

Recently, there has been increasing interest in minimally invasive and percutaneous replacement of cardiac valves. Such surgical techniques involve making a very small opening in the skin of the patient into which a valve assembly is inserted in the body and delivered to the heart via a delivery device similar to a catheter. This technique is often preferable to more invasive forms of surgery, such as the open-heart surgical procedure described above. In the context of pulmonary valve replacement, U.S. Patent Application Publication Nos. 2003/0199971 A1 and 2003/0199963 A1, both filed by Tower, et al., describe a valved segment of bovine jugular vein, mounted within an expandable stent, for use as a replacement pulmonary valve. The replacement valve is mounted on a balloon catheter and delivered percutaneously via the vascular system to the location of the failed pulmonary valve and expanded by the balloon to compress the valve leaflets against the right ventricular outflow tract, anchoring and sealing the replacement valve. As described in the articles: "Percutaneous Insertion of the Pulmonary Valve", Bonhoeffer, et al., Journal of the American College of Cardiology 2002; 39: 1664-1669 and "Transcatheter Replacement of a Bovine Valve in Pulmonary Position", Bonhoeffer, et al., Circulation 2000; 102: 813-816, the replacement pulmonary valve may be implanted to replace native pulmonary valves or prosthetic pulmonary valves located in valved conduits.

Various types and configurations of prosthetic heart valves are used in percutaneous valve procedures to replace diseased natural human heart valves. The actual shape and configuration of any particular prosthetic heart valve is dependent to some extent upon the valve being replaced (i.e., mitral valve, tricuspid valve, aortic valve, or pulmonary valve). In general, the prosthetic heart valve designs attempt to replicate the

function of the valve being replaced and thus will include valve leaflet-like structures used with either bioprostheses or mechanical heart valve prostheses. In other words, the replacement valves may include a valved vein segment that is mounted in some manner within an expandable stent to make a stented valve. In order to prepare such a valve for percutaneous implantation, the stented valve can be initially provided in an expanded or uncrimped condition, then crimped or compressed around the balloon portion of a catheter until it is as close to the diameter of the catheter as possible.

Other percutaneously-delivered prosthetic heart valves have been suggested having a generally similar configuration, such as by Bonhoeffer, P. et al., "Transcatheter Implantation of a Bovine Valve in Pulmonary Position." Circulation, 2002; 102:813-816, and by Cribier, A. et al. "Percutaneous Transcatheter Implantation of an Aortic Valve Prosthesis for Calcific Aortic Stenosis." Circulation, 2002; 106:3006-3008, the disclosures of which are incorporated herein by reference. These techniques rely at least partially upon a frictional type of engagement between the expanded support structure and the native tissue to maintain a position of the delivered prosthesis, although the stents can also become at least partially embedded in the surrounding tissue in response to the radial force provided by the stent and balloons used to expand the stent. Thus, with these transcatheter techniques, conventional sewing of the prosthetic heart valve to the patient's native tissue is not necessary. Similarly, in an article by Bonhoeffer, P. et al. titled "Percutaneous Insertion of the Pulmonary Valve." J Am Coll Cardiol, 2002; 39:1664-1669, the disclosure of which is incorporated herein by reference, percutaneous delivery of a biological valve is described. The valve is sutured to an expandable stent within a previously implanted valved or non-valved conduit, or a previously implanted valve. Again, radial expansion of the secondary valve stent is used for placing and maintaining the replacement valve.

Although there have been advances in percutaneous valve replacement techniques and devices, there is a continued desire to provide different designs of cardiac valves that can be implanted in a minimally invasive and percutaneous manner. It is additionally desirable to provide valves that are resistant to migration after they are implanted.

SUMMARY

The replacement heart valves of the invention each include a stent to which a valve structure is attached. The stents of the invention include a wide variety of structures and features that can be used alone or in combination with features of other stents of the invention. Many of the structures are compressible to a relatively small diameter for percutaneous delivery to the heart of the patient, and then are expandable either via removal of external compressive forces (e.g., self-expanding stents), or through application of an outward radial force (e.g., balloon expandable stents). The devices delivered by the delivery systems described herein can be used to deliver stents, valved stents, or other interventional devices such as ASD (atrial septal defect) closure devices, VSD (ventricular septal defect) closure devices, or PFO (patent foramen ovate) occluders.

Methods for insertion of the replacement heart valves of the invention include delivery systems that can maintain the stent structures in their compressed state during their insertion and allow or cause the stent structures to expand once they are in their desired location. In addition, delivery methods of the invention can include features that allow the stents to be retrieved for removal or relocation thereof after they have been deployed or partially deployed from the stent deliv-

ery systems. The methods may include implantation of the stent structures using either an antegrade or retrograde approach. Further, in many of the delivery approaches of the invention, the stent structure is rotatable in vivo to allow the stent structure to be positioned in a desired orientation.

The stent structures of the invention can provide resistance to leaflet abrasion via the configuration of the wires or other structural elements relative to each other. Other stent structures can provide for reduced crown density and various other configurations of wire shapes and features for use with attached valves for valve replacement procedures.

BRIEF DESCRIPTION OF THE DRAWINGS

The present invention will be further explained with reference to the appended Figures, wherein like structure is referred to by like numerals throughout the several views, and wherein:

FIG. **1** is a front view of an embodiment of a stent in accordance with the invention;

FIG. **2** is a front view of an embodiment of a stent in accordance with the invention;

FIG. **3** is a front view of an embodiment of a stent in accordance with the invention;

FIG. **4** is a perspective view of a stent embodiment in accordance with the invention;

FIG. **5** is a top view of another stent embodiment;

FIG. **6** is a front view of another stent embodiment;

FIG. **7** is a front view of another stent embodiment;

FIG. **8** is a perspective view of another stent embodiment;

FIG. **9** is a perspective view of a stent embodiment having extending elements and positioned on a mandrel;

FIG. **10** is a front view of an exemplary delivery system that can be used for delivering a stent of the type illustrated in FIG. **9**;

FIG. **11-13** are enlarged front views of a portion of a delivery system for delivering a stent of the type shown in FIG. **9**, including three sequential delivery steps;

FIG. **14** is a front schematic view of a stent positioned in an aorta;

FIGS. **15-18** are perspective views of different stent embodiments, each positioned within a heart vessel;

FIG. **19** is a front view of a stent embodiment;

FIG. **20** is a front view of a stent embodiment;

FIG. **21** is a top view of the stent of FIG. **20**;

FIG. **22** is a schematic front view of the stent of FIG. **20** positioned in a heart vessel;

FIG. **23** is a front view of another stent embodiment;

FIG. **24** is a side view of the stent of FIG. **23**;

FIG. **25** is a perspective view of the stent of FIG. **23**, positioned on a mandrel;

FIG. **26** is a top view of the stent of FIG. **23** positioned relative to a schematic view of a heart vessel, wherein the stent includes leaflets in its interior portion;

FIG. **27** is a top view of the stent of FIG. **23**;

FIG. **28** is a perspective top view of the stent of FIG. **23** positioned in a heart;

FIG. **29** is a front view of another embodiment of a stent positioned on a mandrel;

FIGS. **30** and **31** are front and perspective views respectively, of a solid model of a stent of the type illustrated in FIG. **29**;

FIGS. **32** and **33** are front perspective views, respectively, of a stent embodiment;

FIGS. **34** and **35** are front views of a valved stent of the invention;

FIG. **36** is a schematic front view of a stent assembly being delivered to a heart valve;

FIG. **37** is a front view of a stent assembly positioned in a heart valve;

FIG. **38** is a front view of the stent assembly shown in FIGS. **36** and **37**;

FIG. **39** is a front view of a stent assembly having a length L positioned in a heart vessel;

FIG. **40** is a top view of another stent embodiment positioned relative to a schematic view of an anatomical position in a heart;

FIG. **41** is a top view of another stent embodiment;

FIG. **42** is a top view of another stent positioned relative to the interventricular septum and the mitral apparatus;

FIGS. **43-45** are perspective views of additional stent embodiments;

FIG. **46** is a front view of another stent embodiment;

FIGS. **47-50** are front schematic views of embodiments of stents positioned in a heart vessel;

FIGS. **51-53** are front views of a different stents positioned relative to a portion of a heart valve that is cut-away for clarity; and

FIG. **54** is a top cross-sectional view of a valve attached within a stent frame.

DETAILED DESCRIPTION

As referred to herein, the prosthetic heart valves used in accordance with various devices and methods of heart valve delivery may include a wide variety of different configurations, such as a prosthetic heart valve having tissue leaflets or a synthetic heart valve having polymeric, metallic, or tissue-engineered leaflets, and can be specifically configured for replacing any heart valve. That is, while much of the description herein refers to replacement of aortic valves, the prosthetic heart valves of the invention can also generally be used for replacement of native mitral, pulmonic, or tricuspid valves, for use as a venous valve, or to replace a failed bioprosthesis, such as in the area of an aortic valve or mitral valve, for example.

Although each of the valves used with the delivery devices and methods described herein would typically include leaflets attached within an interior area of a stent, the leaflets are not shown in many of the illustrated embodiments for clarity purposes. In general, the stents described herein include a support structure comprising a number of stent or wire portions arranged relative to each other to provide a desired compressibility, strength, and leaflet attachment zone(s) to the heart valve. Other details on particular configurations of the stents of the invention are also described below; however, in general terms, stents of the invention are generally tubular support structures, and leaflets will be secured to the support structure to provide a valved stent. The leaflets can be formed from a variety of materials, such as autologous tissue, xenogaph material, or synthetics as are known in the art. The leaflets may be provided as a homogenous, biological valve structure, such as a porcine, bovine, or equine valve. Alternatively, the leaflets can be provided independent of one another (e.g., bovine or equine pericardial leaflets) and subsequently assembled to the support structure of the stent. In another alternative, the stent and leaflets can be fabricated at the same time, such as may be accomplished using high strength nano-manufactured NiTi films of the type produced at Advanced Bio Prosthetic Surfaces Ltd. (ABPS) of San Antonio, Tex., for example. The support structures are generally configured to

accommodate three leaflets; however, the replacement prosthetic heart valves of the invention can incorporate more or less than three leaflets.

In more general terms, the combination of a support structure with one or more leaflets can assume a variety of other configurations that differ from those shown and described, including any known prosthetic heart valve design. In certain embodiments of the invention, the support structure with leaflets utilize certain features of known expandable prosthetic heart valve configurations, whether balloon expandable, self-expanding, or unfurling (as described, for example, in U.S. Pat. Nos. 3,671,979; 4,056,854; 4,994,077; 5,332,402; 5,370,685; 5,397,351; 5,554,185; 5,855,601; and 6,168,614; U.S. Patent Application Publication No. 2004/0034411; Bonhoeffer P. et al., "Percutaneous Insertion of the Pulmonary Valve", Pediatric Cardiology, 2002; 39:1664-4669; Anderson H R, et al., "Transluminal Implantation of Artificial Heart Valves", EUR Heart J., 1992; 13:704-708; Anderson, J. R., et al., "Transluminal Catheter Implantation of New Expandable Artificial Cardiac Valve", EUR Heart J., 1990, 11: (Suppl) 224a; Hilbert S. L., "Evaluation of Explained Polyurethane Trileaflet Cardiac Valve Prosthesis", J Thorac Cardiovascular Surgery, 1989; 94:419-29; Block P C, "Clinical and Hemodynamic Follow-Up After Percutaneous Aortic Valvuloplasty in the Elderly", The American Journal of Cardiology, Vol. 62, Oct. 1, 1998; Boudjemline, Y., "Steps Toward Percutaneous Aortic Valve Replacement", Circulation, 2002; 105:775-558; Bonhoeffer, P., "Transcatheter Implantation of a Bovine Valve in Pulmonary Position, a Lamb Study", Circulation, 2000: 102:813-816; Boudjemline, Y., "Percutaneous Implantation of a Valve in the Descending Aorta In Lambs", EUR Heart J, 2002; 23:1045-1049; Kulkinski, D., "Future Horizons in Surgical Aortic Valve Replacement: Lessons Learned During the Early Stages of Developing a Transluminal Implantation Technique", ASAIO J, 2004; 50:364-68; the teachings of which are all incorporated herein by reference).

Orientation and positioning of the stents of the invention may be accomplished either by self-orientation of the stents (such as by interference between features of the stent and a previously implanted stent or valve structure) or by manual orientation of the stent to align its features with anatomical or previous bioprosthetic features, such as can be accomplished using fluoroscopic visualization techniques, for example. For example, when aligning the stents of the invention with native anatomical structures, they should be aligned so as to not block the coronary arteries, and native mitral or tricuspid valves should be aligned relative to the anterior leaflet and/or the trigones/commissures.

Some embodiments of the support structures of the stents described herein can be a series of wires or wire segments arranged so that they are capable of transitioning from a collapsed state to an expanded state. In some embodiments, a number of individual wires comprising the support structure can be formed of a metal or other material. These wires are arranged in such a way that a support structure allows for folding or compressing to a contracted state in which its internal diameter is greatly reduced from its internal diameter in an expanded state. In its collapsed state, such a support structure with attached valves can be mounted over a delivery device, such as a balloon catheter, for example. The support structure is configured so that it can be changed to its expanded state when desired, such as by the expansion of a balloon catheter. The delivery systems used for such a stent should be provided with degrees of rotational and axial orientation capabilities in order to properly position the new stent at its desired location.

The wires of the support structure of the stents in other embodiments can alternatively be formed from a shape memory material such as a nickel titanium alloy e.g., Nitinol) or a very high-tensile material that will expand to its original state after compression and removal of external forces. With this material, the support structure is self-expandable from a contracted state to an expanded state, such as by the application of heat, energy, and the like, or by the removal of external forces (e.g., compressive forces). This support structure can be repeatedly compressed and re-expanded without damaging the structure of the stent. In addition, the support structure of such an embodiment may be laser cut from a single piece of material or may be assembled from a number of different components. For these types of stent structures, one example of a delivery system that can be used includes a catheter with a retractable sheath that covers the stent until it is to be deployed, at which point the sheath can be retracted to allow the stent to expand. Alternatively, the stent structures of the invention can be implanted using conventional surgical techniques and/or minimally invasive surgical procedures. In such cases, the stents of the invention can advantageously require relatively few or no sutures to secure the stent to an anatomical location within the patient.

Referring now to the Figures, wherein the components are labeled with like numerals throughout the several Figures, and initially to FIGS. **1-5** illustrate stents **10**, **20**, **30**, and **40**, respectively, each of which is positioned over a mandrel. With particular reference to FIG. **1**, stent **10** includes a first end **12** having six crowns and a second end **14** having twelve crowns. Each of the stent crowns at the second end **14** includes a loop or eyelet **19** that can be used for attachment to a delivery system and/or tissue valve, for example. It is contemplated that each of the crowns at the second end includes a loop or eyelet **19**, as shown, or that only some of the crowns include such a loop or eyelet. The size and shape of the loops **19** can all be the same on a single stent, or they can have different sizes and/or shapes. Stent **10** further includes at least one longitudinal post **16**, which can be used for attachment of tissue to the stent, along with providing additional stability to the first end **12** of the stent. The longitudinal post **16** extends generally along the annular region of the stent **10** and has a height that accommodates attachment of leaflet material. That is, the height of the post **16** is generally the same as the desired commissural height for the stent **10**. As shown, the longitudinal posts **16** are comprised of two bars or vertical portions that are spaced from each other by a sufficient distance to allow leaflets to be drawn between the vertical portions at the leaflet commissures. Other skirt material portions and/or commissure protection features can also be drawn through the space between the vertical portions. The space between the vertical portions of each post **16** may have incremental steps **18**, as shown in FIG. **1**, which help to provide anchoring points for suturing, for example, or the posts may not include such steps, as shown with post **132** in FIG. **3**, which will be discussed in farther detail below. If steps **18** are provided, they can be generally perpendicular to the vertical posts, which will make the openings generally rectangular in shape, or the steps can be differently oriented and shaped so that the openings are circular, elliptical, or another chosen shape. It is further noted that the vertical portions of the posts **16** can be made of a different material or have a different thickness than the rest of the stent wires and/or the posts can be made with reinforced attachment stents or welds on the outflow end to provide additional strength in this area.

With this stent **10**, wire structure extends between one end of the post **16** and the first end **12** (which may be referred to as the aortic aspect of the stent) and additional wire structure

extends between the other end of the stent post and the second end **14** (which may be referred to as the ventricular aspect of the stent). The stent **10** may include one longitudinal post **16** for each commissure of the valve that will be attached thereto, if desired. That is, for a three-leaflet valve, three longitudinal posts **16** will be provided.

The stent **20** of FIG. **2** includes multiple wires that are arranged in a generally similar configuration to that discussed above relative to FIG. **1**. However, stent **20** further includes a central bulbous region between its first and second ends **22**, **24** that is larger in diameter than the diameters of the first and second ends of the stent. The bulbous region can be configured to generally =ten the contours of the anatomy where the stent will be positioned in the patient (e.g., at the aortic valve sinus region). The first end **22** is flared inwardly (i.e., toward the central axis of the stent), preferably by an amount that is enough to be atraumatic, but not so pronounced that it loses contact with the patient's anatomy or interferes with another device (e.g., a coronary catheter) at a later date. Thus, the inward flare can be less than that shown, although it is possible that the flare is even greater than that shown. In addition, the second end **24** is slightly flared outwardly, as shown in the Figure. This flare at the second end **24** of the stent **20** (i.e., away from the central longitudinal axis of the stent) can prevent or minimize leakage between the implanted heart valve and the native annulus and/or to provide a physical and/or visual docking feature to secure the stent against a wall of a vessel or opening in the heart to prevent migration of the stent, for example. Additionally, the second end **24** can also have an at least slightly inward bend (see FIG. **3**, for example) that may be advantageous when implanting this stent in the aortic region in order to minimize trauma to adjacent anatomical structures (e.g., the mitral valve anterior leaflet or the left ventricular wall). This slight inward bend can also help to minimize pressure on the septum in the area of the bundle branch, which can in turn reduce the potential for arrhythmias or heart block during or after the transcatheter valve replacement procedure.

FIGS. **3** and **4** illustrate stents **30** end **40** that are "selectively" flared to match particular desired shapes for portions of the stent. For example, certain stent wires are flared outwardly to avoid potential interference between the stent and the tissue leaflets of the replacement valves. The stent features to which the tissue will be attached may not be flared at all, such that the stent is relatively tubular, or these wires could instead be flared inwardly or outwardly. Stents **30**, **40** include central regions **34**, **44**, respectively that are somewhat larger in diameter than the adjacent portions of the stent. The stent **30** further includes at least one longitudinal element or feature that can be used for attachment of tissue to the stent, such as a longitudinal post **32**. Such posts **32** can also be positioned at the same distance from the longitudinal axis as the other stent elements in the central region **34**, or the longitudinal posts can be closer to or further from the central axis of the stent than the other stent elements in the central region **34**, if desired. By positioning the posts closer to the central axis than the other wires in the central region **34**, the free edges of the dynamic leaflets positioned inside the stent **30**, **40** of the new or replacement valve would be less likely to contact the stent posts when the valve leaflets are fully open. This reduced contact can reduce the potential for wear on the leaflets during valve cycling. An additional benefit of positioning the wires of the post closer to the central longitudinal axis as the other stent wires is to minimize stress at the commissures, and to help maintain coronary perfusion. This can be accomplished by limiting the opening of the leaflet so that coronary flow behind the valve leaflets is maintained. Yet another benefit of these configurations having attachment points that are inwardly offset from the largest outer diameter of the stent is that a smaller tissue valve can be used, which in turn reduces the overall transcatheter crimp profile of the delivery system.

Reduction of the potential wear on the valve leaflets can alternatively be accomplished by fastening leaflet commissures closer to the center of the stent than to the outer circumference. FIG. **54** illustrates such an arrangement with a schematic view of an outer stent frame **400** having three leaflets **402** arranged so that each two adjacent leaflets are attached to the stent frame **400** at a leaflet commissure area **404**. Another fastening point of each of these sets of leaflets **402** at the commissure area **404** is shifted inwardly toward the center of the stent frame **400** to an inner fastening point **406**. In this way, when the leaflets **402** are open, their free edges can only move out as far as the circle or inner area **408**, which is shown schematically with a broken line. As shown, even if the leaflets **402** are in this fully open position, they will not contact the outer stent frame **400**, thereby reducing potential wear on the valve leaflets.

Stents **10**, **20**, and **40** each include an arrangement of wires that provides twelve stent crowns at one end and six stent crowns at the opposite end, while stent **30** includes twelve crowns at both ends. For embodiments that include twelve crowns at the inflow end of the steal, this configuration can provide additional strength to the stent annulus area to prevent migration, to open stenotic native valve orifices, and also to provide a greater number of points for attaching pericardial leaflets to the stent. It is possible, however, to provide less than twelve (e.g., six) crowns at the outflow because the same stent strength is not required at this end for less tissue attachment points are needed. These illustrated stents are only some of the arrangements of wires that can achieve this feature of having different numbers of steal crowns at opposite ends of a single stent. In a further alternative, each of the ends of one stent can have the same number of stent crowns, but the center portion can have a more or less dense concentration of wires than either of the ends. In any case, a stent having less stent crowns at one of its ends may simplify the use of an associated delivery system, since the end with less stent crowns will have a corresponding smaller number of crowns that need to be connected to the delivery system.

FIGS. **5-8** illustrate additional stent embodiments **80**, **60**, **70**. Stent **60** has a similar shape to the stent **20** of FIG. **2**; however, stent **60** includes the same number of stent crowns at both ends, and also does not have the same longitudinal posts that are part of the wire arrangement of stent **20**. Rather, stent **60** includes a generally regular diagonal crisscross wire pattern along its entire length, and further includes multiple eyelets or hooks **62** at one end. A first stent end **64** is flared generally inwardly and a second spent end **66** is contoured both inwardly and outwardly as compared to the central region of the stent. Stent **70** includes a bulbous shape to the wires at one end, eyelets or hoops at the opposite end, and differing numbers of stent crowns at the opposite ends of the stent. Stent **80** includes pocket portions **82** that provide attachment points for the leaflets **84** that are positioned inwardly from the outer diameter of the stent **80**. Again, these inwardly located attachment points will reduce the potential for leaflet abrasion and moves the commissure attachment points to an area that that puts less stress on the leaflets. Finally, the pockets **82** provide an area where the suture knots can be positioned so that they do not increase the overall crimp profile of the valve.

FIG. **9** illustrates another stent embodiment **90** that includes several features described above relative to stent

crowns, longitudinal posts, incremental steps on at least one of the posts and the wire. Stent **90** also includes at least one longitudinal stent post **92** comprised of two vertical bars speed from each other. Stent **90** further includes three wings **94**, each of which extends outwardly from the stent body and between two longitudinal posts **92**. The longitudinal posts **92** can be positioned inwardly of the outer diameter of the stent **90** to provide the advantages discussed above relative to avoiding leaflet abrasion and the like. These wings can be used to dock the stent against the top aspect of the native leaflets when the stent is implanted. Again, this stent has differing numbers of crowns at its opposite ends, and hooks or eyelets on the crowns at one end.

FIGS. **10-13** illustrate a portion of one exemplary delivery system **100** for delivering a stent having wings, such as stent **90**. In particular, FIG. **10** shows a delivery system tip including a fully crimped stent enclosed within a main catheter sheath. FIG. **11** shows the wings **94** being deployed from the delivery system **100** by retracting the main catheter sheath **102**. In an implantation, the wings **94** can be positioned to interface with the outflow aspect of the native valve leaflets. Once these wings **94** are in contact with the native valve leaflets, the inflow or annular end of the stent is deployed by driving the catheter tip forward, as illustrated in FIG. **12**. The native leaflets will now contact the wings **94** and inflow end of the stent **90**, thereby minimizing the potential for migration of the replacement valve. The outflow end of the stent can now be deployed, as shown in FIG. **13**, to fully re-expand the stent **90** release it from the delivery system, which is accomplished by further retracting the main catheter sheath.

FIG. **14** illustrates a stent **110** that includes a highly flexible delivery system attachment end **112** that enables the portion of the stent **110** that interfaces with the anatomy to create secure fixation to be fully deployed while still attached to the delivery system. This system enables a sprocket-style delivery system attachment mechanism that can help to minimize the delivery system diameter size. A sprocket-style delivery system includes some type of inner core member from which multiple protrusions extend, where the shape of the protrusions allow for engagement with wires of a stent. Stent **110** does not require attachment of each crown on the aortic end of the stent, while still enabling the ventricular region of the stent to fully deploy to assess functionality and positioning, which can thereby allow for a smaller diameter for the delivery system. As shown, stent **110** is positioned relative to an aorta **114**, and stent **110** includes an outflow end that has very flexible struts that enable the anchoring portion of the stent to be fully deployed to assess the valve functionality and positioning, while still being captured on a sprocket-style delivery system. The outer diameter of the stent can preferably expand to match the maximum inner diameter of the anchoring region.

FIG. **15** illustrates another embodiment of a stent **120** having a central region **122** with a diameter that is larger than the diameter at either of the ends. A first end **124** has six stent crowns, while the opposite second end **126** has twelve stent crowns, each of which includes an eyelet **128**. With such an arrangement, the number of crowns provided at the outflow end of the stent is reduced, thereby requiring fewer points for attachment to a delivery system. FIG. **16** illustrates another stent embodiment **130** including flared regions at both ends and a central region that is generally cylindrical.

FIG. **17** illustrates another embodiment of a stent **140** that is positioned at the aortic valve position of a heart. Stent **140** includes six stent crowns at one end and twelve stent crowns at the opposite end, and further includes a central area with a relatively large opening or gap **142** between the wires. The gap **142** can be positioned at the coronary ostia so as to not obstruct or interfere with blood flow. The stents **120**, **130**, **140**, along with many of the other stent embodiments described herein, are designed to match with native anatomic features of a patient to improve resistance to migration and improve paravalvular replacement valve sealing.

FIG. **18** illustrates another embodiment of a stent **150** that is designed for anatomic compatibility and includes a bulbous portion that is positioned to sit generally at the annular area of a vessel. A ring **152** shown in this figure is a sealing gasket on the outside of the stent and is positioned generally at the annulus of a vessel when implanted. The gasket can be made of fabric or inflatable tube structures, for example.

FIG. **19** illustrates a stent **160** that does not include many of the contours described relative to other stent embodiments of the invention, but includes longitudinal posts **162** for attachment of the valve tissue. Posts **162** are comprised of two longitudinal wire portions **166** spaced from each other, and further include optional intermediate members **168** that extend between the longitudinal portions **166**. The outer structure ring structure shown in this drawing is provided as an illustration of the general stitching path that can be used for tissue material within the stent.

FIGS. **20-22** illustrate an embodiment of a stent **180** that includes a number of features described above for the stents of the invention, along with additional features. In particular, FIG. **20** shows the stent **180** with longitudinal posts **182** extending in the direction of the length of the stent **180**, and a region **184** at one end that is bulbous or has a larger diameter than the central portion of the stent. The opposite end of the stent **180** includes flared portions **186** that extend from opposite sides of the generally tubular central portion. As shown in FIG. **21**, each flared portion **186** can include two crowns, although it is possible that the flared portion **186** can be configured somewhat differently than shown (e.g., there can be more or less crowns, the crowns can be shaped differently, the flared portion **186** can extend around a larger or smaller portion of the circumference of the stent, and the like). As is further illustrated in FIG. **20**, the geometry of the stent can be designed to incorporate optimal attachment points for tissue. That is, the stent node trajectory can be specifically selected to provide the desired points for the attachment of tissue. Such a feature can be considered and designed for tents including longitudinal posts, as shown in FIG. **20**, and may also be considered for stents comprising more diamond-shaped wire patterns without longitudinal posts.

The outer profile of stent **180** is shown in an exemplary position within the anatomy (i.e., aorta) of a patient in FIG. **22**, with the central area that includes the commissural posts being positioned in the bulbous area of an aorta. The flares **186** extend into the ventricle in order to help anchor the stent **180** in place. The flares **186** are preferably positioned in locations where they do not disrupt the native anatomical function. That is, the flares **186** should not interfere with the mitral valve anterior leaflet and should not apply pressure to the septum in the area of the conduction system bundle branch. Again, it is also preferable that the central portion of the stent **180** does not contact the native aortic sinus region, in order to minimize the potential for coronary occlusion or obstruction.

It is noted that in many of the stent embodiments shown and described herein, the aspect ratio of certain portions of the stent is exemplary, and can be somewhat different from that shown. It is further noted that if the stent of any of the embodiments is to be positioned to replace the aortic valve, the stent can be provided with a lower density wire portion in the area where the coronaries are located. To eliminate the need to

clock the device, reduced wire density around the entire perimeter of the stent in the central area can be provided. Further, stent embodiments described herein may be Modified to include additional structure for attachment of tissue for the valve, such as the vertical stent posts described in many of the embodiments.

FIGS. **21-28** illustrate another embodiment of a stent **200** that includes a central cylindrical portion with at least two regions with a lower density of wires, each of which is provided for positioning in the area of the coronary openings. The wires of this lower density area are arranged to provide openings **202** that are larger than the spaces between other wires of the stent. These openings are offset along the length of the stent to be arranged in a zigzag type of pattern around the circumference of the stent **120**. One end of the stent **200** includes flared portions **204** that extend from opposite sides of the central cylindrical portion of the stent. Each flared portion **204** includes three crowns, although variations of this configuration are contemplated, as discussed above relative to flared stent portions. As shown in FIG. **26**, stent **200** is positioned relative to a mitral valve **210** so that one of the flared portions is positioned at the left ventricle, and one of the openings in the stent is positioned at the left coronary artery. FIG. **27** is a top view of the stent **190**, and FIG. **28** shows one exemplary position of the stent **190** relative to the anatomy of a patient, including the septum and anterior leaflet of the mitral valve.

FIG. **29** illustrates a stent **220** that includes openings **222** (i.e., areas of lower wire density) for the coronaries, and further includes sub-annular and supra-annular circumferential wings to help secure the stent to the patient's native anatomy. In particular, the area below the openings **222** includes an outward curve or flare to create a wing **224** that can extend around all or part of the circumference of the stent **220**. The wires then curve back toward the central longitudinal axis of the stent, then curve or flare outwardly again to create a wing **226** that can extend around all or a part of the circumference of the stent **220**. As shown, the wings **224**, **226** and the area between them form a generally sinusoidal configuration, where the wing **224** can be positioned above an annulus and wing **226** can be positioned below that annulus to provide the anchoring for a more secure attachment in that position. This series of wings can help to anchor the stent in regions of calcified or fused leaflets in the aortic stenosis patient population. Stent **220** further includes imaging markers **228** that can be used to identify the high and low points of the commissures, the annular (valve) plane of the implant, and/or other features. Markers can also be used to identify high and low boundaries for optimal implant placement within the patient's anatomy.

FIGS. **30** and **31** are solid models of a stent **240** that is configured similarly to the stent of FIG. **29**, including the sinusoidal shape at one end that creates wing areas. These wings can have a different profile from that shown, although it is preferable in this embodiment that there are sinusoidal "peaks" **242**, **244** that are separated by a "valley" **246**, where the annulus of a valve can be positioned in the valley **246** so that the peaks **242**, **244** are on opposite sides of the annulus. The peaks and valleys can have different heights than shown, and the spacing between the peaks may also be different. That is, the spacing between the sub-annular and supra-annular flares can be varied, depending on the specific procedure that will be performed and the desired characteristics of the stent. These embodiments, along with other shaped stents described herein, can help to minimize stent migration within the patient due to the ability of the stent to conform to various contours of the patient's anatomy. FIG. **30** also illustrates an optional groove **248** that can be positioned generally around the periphery of the stent **240** to match the native 3-dimensional configuration of the native anatomy. A gasket **250** can be positioned within the groove **248**, where such a gasket **250** can include one continuous structure that generally follows the shape of the groove **248**, or it can include one or more pieces within portions of the groove **248**. The gasket **250** can improve paravalvular sealing. Further, the gasket **250** can be made of a material that can heal into the native tissue of the patient, which can help the stent to resist migration.

FIGS. **32** and **33** illustrate another stent embodiment **240** that includes flares at both the sub-annular and sinotubular junction (STJ) areas. The illustrated stent further includes vertical stent posts, twelve inflow crowns and six outflow crowns although there could be more or less than these numbers of inflow and outflow crowns. Stent **240** has a wire arrangement similar to that shown for the stents of FIGS. **1-4** and other stents described and shown herein; however, the central area of stent **240** is more tubular or "straight," with slightly curved areas at both ends.

One exemplary stent of the invention combines the following features: eyelets at one end for attachment to the delivery system and tissue valve; vertical commissural tissue attach stents or posts; moderately flared non-commissural attach vertical stents or STJ flare; sub-annular flares; inflow and outflow atraumatic curvatures; a twelve crown inflow; and six tapered crowns at the outflow end. Such an embodiment of a stent is illustrated, for example, as stent **250** in FIGS. **34** and **35**. Stent **250** further includes tissue material **252** attached within its internal area to provide leaflets for the valve. Two spaced-apart vertical members are used to make up vertical posts **254**, one of which is most visible in FIG. **35**. One exemplary pattern for stitching the tissue to the vertical post **254** is also illustrated, although the stitching pattern can differ from that shown.

Delivering any balloon-expandable stents of the invention to the implantation location can be performed percutaneously. In general terms, this includes providing a transcatheter assembly, including a delivery catheter, a balloon catheter, and a guide wire. Some delivery catheters of this type are known in the art, and define a lumen within which the balloon catheter is received. The balloon catheter, in turn, defines a lumen within which the guide wire is slideably disposed. Further, the balloon catheter includes a balloon that is fluidly connected to an inflation source. It is noted that if the stent being implanted is the self-expanding type of stent, the balloon would not be needed and a sheath or other restraining means would be used for maintaining the stent in its compressed state until deployment of the stent, as described herein. In any case, for a balloon-expandable stent, the transcatheter assembly is appropriately sized for a desired percutaneous approach to the implantation location. For example, the transcatheter assembly can be sized for delivery to the heart valve via an opening at a carotid artery, a jugular vein, a sub-clavian vein, femoral artery or vein, or the like. Essentially, any percutaneous intercostals penetration can be made to facilitate use of the transcatheter assembly.

Prior to delivery, the stent is mounted over the balloon in a contracted state to be as small as possible without causing permanent deformation of the stent structure. As compared to the expanded state, the support structure is compressed onto itself and the balloon, thus defining a decreased inner diameter as compared to an inner diameter in the expanded state. While this description is related to the delivery of a balloon-expandable stent, the same basic procedures can also be applicable to a self-expanding stent, where the delivery system would not include a balloon, but would preferably

include a sheath or some other type of configuration for maintaining the stent in a compressed condition until its deployment.

With the stent mounted to the balloon, the transcatheter assembly is delivered through a percutaneous opening (not shown) in the patient via the delivery catheter. The implantation location is located by inserting the guide wire into the patient, which guide wire extends from a distal end of the delivery catheter, with the balloon catheter otherwise retracted within the delivery catheter. The balloon catheter is then advanced distally from the delivery catheter along the guide wire, with the balloon and stent positioned relative to the implantation location. In an alternative embodiment, the stent is delivered to an implantation location via a minimally invasive surgical incision (i.e., non-percutaneously). In another alternative embodiment, the stent is delivered via open heart/chest surgery. In one embodiment of the stents of the invention, the stent includes a radiopaque, echogenic, or MRI visible material to facilitate visual confirmation of proper placement of the stent. Alternatively, other known surgical visual aids can be incorporated into the stent. The techniques described relative to placement of the stent within the heart can be used both to monitor and correct the placement of the stent in a longitudinal direction relative to the length of the anatomical structure in which it is positioned.

Once the stent is properly positioned, the balloon catheter is operated to inflate the balloon, thus transitioning the skin to an expanded state. Alternatively, where the support structure is formed of a shape memory material, the stent can self-expand to its expanded state.

One or more markers on the valve, along with a corresponding imaging system (e.g., echo, MRI, etc.) can be used with the various repositionable delivery systems described herein in order to verify the proper placement of the valve prior to releasing it from the delivery system. A number of factors can be considered, alone or in combination, to verify that the valve is properly placed in an implantation site, where some exemplary factors are as follows: (1) lack of paravalvular leakage around the replacement valve, which can be advantageously examined while blood is flowing through the valve since these delivery systems allow for flow through and around the valve; (2) optimal rotational orientation of the replacement valve relative to the coronary arteries; (3) the presence of coronary flow with the replacement valve in place; (4) correct longitudinal alignment of the replacement valve annulus with respect to the native patient anatomy; (5) verification that the position of the sinus region of the replacement valve does not interfere with native coronary flow; (6) verification that the sealing skirt is aligned with anatomical features to minimize paravalvular leakage; (7) verification that the replacement valve does not induce arrhythmias prior to final release; and (8) verification that the replacement valve does not interfere with function of an adjacent valve, such as the mitral valve.

FIGS. **36-39** are schematic views of various embodiments of stents of the present invention. In particular, FIG. **36** illustrates a stent assembly **280** that includes features that align and secure it with specific anatomical features in the left ventricle region and the left ventricular outflow tract region of a patient. Stent assembly **280** includes a stented valve **282** from which tethers **284** extend. Tethers **284** are preferably flexible to accommodate curvature of the native aorta above the valve annulus. Optional anchors **286** are shown at the distal ends of the stent. More specifically, each of the tethers **284** extends from one of the commissures **288** of the stent **282**. The stent assembly **280** further includes a distal element such as a stent graft **290** positioned between the tethers **284** near the anchors **286**, which is flexible and can accommodate widely varying patient anatomy. The stent graft **290** will be positioned distal to the sinus area of the left ventricular outflow tract when implanted. This configuration can facilitate stabilization of the stent assembly and may be designed to register or interface with another stent gait that is implanted at a later time.

This stent assembly **280** can include flexible connections between annular and supra-annular stent aspects. The flexible connections may be elastomeric, fabric, metal, or the like. Such flexible connections can help the stent assembly to accommodate most varying anatomy above the sinotubular junction and also to accommodate aortic curvature. In addition, the flexible connections can make the stent assembly able to accommodate anerysmal aortas.

The stent assembly **280** may further include a gasket **294** positioned adjacent an end of the steeled valve **282**. In addition, when the stent assembly is implanted in a patient, a plaque pocket **296** can be created that provides embolic protection by creating a volume that can entrap plaque, calcification, and other embolic from traveling in a distal direction and causing a thromembolic event, such as a stroke.

Alternatively, portions of the system may be designed to include a longer useful life than others. For example, the frame of the present invention could be designed to have a relatively long useful life (e.g. 20 years), while the tissue component could have a relatively shorter useful life (e.g. 10 years).

An embolic protection device **292** can be provided distal to the stent assembly **280**, as is shown in FIG. **36**. The device **292** can be utilized during the implantation procedure to capture and trap any emboli released and/or generated by the valve procedure, while still maintaining uninhibited or sufficient perfusion through the aorta and coronary arteries during valve implantation. In addition, FIGS. **36-39** illustrate a portion of the stent positioned above the sinotubular junction **284** covered with fabric, polymer, and/or tissue, which can serve this same purpose.

FIGS. **37-39** illustrate alternative views of the stent assembly **280**, both within a heart vessel and independent of anatomical structure (FIG. **38**). It is noted that the anchoring of the stent posts via the anchors **286** can help to prevent valve ejection. FIG. **37** shows the stent assembly **280** implanted in a supra-annular position in a patient's anatomy, which can beneficially improve the orifice area by avoiding the stenotic region of the aorta. FIG. **39** shows the flexibility of the stent graft material in order to conform to the curved area of an aorta.

FIG. **40** illustrates a top view of a stent **300** having a fixation tab **302** positioned in the non-coronary sinus area **310**, and with no such tabs at either the right coronary artery **314** or the left coronary artery **312**. That is, fixation components of stent **300** may secure the system to non-coronary sinus and/or regions of the left ventricle adjacent to the aortic valve annulus. This may avoid obstruction of coronary blood flow and prevent unwanted interaction between the system and the septum and mitral valve anterior leaflet. Further, the fixation tab **302** does not prevent or inhibit subsequent coronary intervention, while providing the advantage of minimizing or preventing migration of the stent toward the aorta. FIG. **41** illustrates a stent having both a fixation tab **302** and flared portions **304** that help to prevent migration of the stent. FIG. **42** illustrates stent **300** having flared regions **304** as positioned relative to the interventricular septum **306** and the mitral valve apparatus **308**.

FIGS. **43-45** illustrate alternative stent embodiments **360**, **370**, **380**, each of which comprises an extending or fixation

tab **364**, **374**, **384**, respectively, along with flared portions **362**, **372**, **382**, respectively. Tab **364** of stent **360** is configured as a bulging wire area, tab **374** of stent **370** comprises an extension that is angled in the same general direction as the wings **372**, and tab **384** of stent **380** comprises an extension that is angled in generally the opposite direction from that of the wings **382**. The stent **370** is illustrated in FIG. **51** with its tab **374** positioned relative to a non-coronary sinus **376**, stent **380** is illustrated in FIG. **52** with its tab **384** positioned relative to a non-coronary sinus **386**, and stent **360** is illustrated in FIG. **53** with its fixation tab **364** positioned relative to a non-coronary sinus **366**. As shown, these tabs can help to prevent stent migration due to their interference with the patient's anatomy.

FIGS. **47** and **48** schematically illustrate the aorta of a patient. As shown, the aorta begins to curve distal to the annulus level. Many typical transcatheter valve stents are cylindrical with a relatively straight axis. Such a stent structure does not easily conform to the native anatomy, which can present a number of potential issues. First, the reduced pressure on the anatomy at the inner portion of the curvature (such as is illustrated with the an area **332** adjacent to a stent **330** in FIG. **49**) can lead to improper seating, migration, and/or paravalvular leakage. Second, increased pressure on the anatomy at the outer portion of the curvature can lead to, or increase the potential for cardiac conduction system block or interference. Third, increased pressure on the anatomy at the outer portion of the curvature can lead to local erosion, irritation, and/or dissection of tissue. Fourth, the stent can be subjected to increased torsional and/or bending stresses and strains, which can affect the short-term structural integrity of the stent. Finally, lack of conformity with the curvature of the native anatomy can inhibit the ability of the clinician to accurately or consistently position the stent/valve in the desired location.

Several stents of the present invention can alleviate this non-conformity of the valve frame with the native anatomy. In one embodiment, the stent could have a predetermined curvature that matches or more closely conforms to the native anatomy, such as stent **335** in FIG. **50**. In other embodiments, the stent could have flexibility (e.g., area **322** of stent **320** in FIGS. **47-48**) or a binged area (e.g., hinge **342** of stent **340** in FIG. **48**) in the portion of the stent that would enable it to conform to the native curved anatomy. FIGS. **46** and **47** illustrate stent designs that incorporate flexibility in their central regions, which in turn enables improved conformity with the native anatomy. The central areas or numbers **322** can be fabricated from a wide variety of materials, such as metals, polymers, fabrics, and the like. The members **322** can include a number of geometries that allow flexibility to conform to the native, curved aortic anatomy. Referring again to FIG. **36**, this stent assembly incorporates elements **287** that are not attached to each other except through flexible materials such as fabric, tissue, or polymeric materials that enable a high degree of conformity with the native anatomy curvature within the ascending aorta.

The present invention also optionally or alternatively includes distal emboli protection features which may be incorporated into a delivery system for delivering a stent assembly (e.g. in the nose assembly), such as the thromboembolic filter. The protection features may provide acute protection during percutaneous valve delivery. The protection features may afford substantially uninhibited flow through coronaries during systole or diastole.

The present invention has now been described with reference to several embodiments thereof. The entire disclosure of any patent or patent application identified herein is hereby incorporated by reference. The foregoing detailed description and examples have been given for clarity of understanding only. No unnecessary limitations are to be understood therefrom. It will be apparent to those skilled in the art that many changes can be made in the embodiments described without departing from the scope of the invention. Thus, the scope of the present invention should not be limited to the structures described herein, but only by the structures described by the language of the claims and the equivalents of those structures.

What is claimed is:

1. A stented valve prosthesis for implantation within a native mitral valve, comprising:

a generally tubular expandable stent structure comprising a first end, a second end, a central body portion having one or more openings, and a longitudinal axis;

a wing portion extending outwardly from the stent structure and away from the longitudinal axis of the stent structure in an expanded deployed configuration,

wherein a radius of the wing portion relative to the longitudinal axis is greater than a radius of the central body portion relative to the longitudinal axis in the expanded deployed configuration, and

wherein the wing portion fits within one of the openings in the central body portion of the stent structure in a crimped delivery configuration; and

a valve structure comprising a plurality of leaflets attached to an interior of the stent structure.

2. The stented valve prosthesis of claim **1**, wherein the wing portion comprises a distal end detached from the stent structure.

3. The stented valve prosthesis of claim **1**, wherein the wing portion extends from the first end of the stent structure and toward the second end of the stent structure.

4. The stented valve prosthesis of claim **1**, wherein the second end of the stent structure comprises a flared portion having a radius greater than the radius of the central body portion.

5. The stented valve prosthesis of claim **1**, wherein the wing portion extends around a majority of a circumference of the first end of the stent structure.

6. The stented valve prosthesis of claim **1**, wherein the wing portion extends toward the first end of the stent structure.

7. The stented valve prosthesis of claim **1**, wherein the wing portion comprises a curve.

8. The stented valve prosthesis of claim **7**, wherein the wing portion curves back toward the longitudinal axis of the stent structure.

9. The stented valve prosthesis of claim **1**, wherein the wing portion is configured to engage an annulus of the native mitral valve.

10. The stented valve prosthesis of claim **1**, further comprising a sealing gasket attached to the stent structure.

11. The stented valve prosthesis of claim **1**, wherein the stent structure is self-expanding.

12. The stented valve prosthesis of claim **1**, wherein the wing portion comprises a plurality of wing components.

13. A stented valve prosthesis for implantation within a native mitral valve, comprising:

a generally tubular stent structure comprising a first end, a second end, a central body portion, and a longitudinal axis;

a wing portion extending outwardly from the first end of the stent structure toward the second end of the stent structure and away from the longitudinal axis of the stent structure over an area of reduced wire density of the stent structure,

wherein a radius of the wing portion relative to the longitudinal axis is greater than a radius of the central body portion relative to the longitudinal axis; and

a valve structure comprising a plurality of leaflets attached to an interior of the stent structure.

14. The stented valve prosthesis of claim **13**, wherein the area of reduced wire density is located in the central body portion of the stent structure.

15. The stented valve prosthesis of claim **13**, wherein a diameter of the second end of the stent structure is greater than a diameter of the central body portion.

16. The stented valve prosthesis of claim **13**, wherein the wing portion comprises a plurality of wing components.

17. A method of implanting a stented valve prosthesis within a native mitral valve, comprising:

inserting a delivery system with the stented valve prosthesis into a body lumen, the stented valve prosthesis comprising:

a generally tubular expandable stent structure comprising a first end, a second end, a central body portion having one or more openings, and a longitudinal axis;

a wing portion extending outwardly from the stent structure and away from the longitudinal axis of the stent structure in an expanded deployed configuration,

wherein a radius of the wing portion relative to the longitudinal axis is greater than a radius of the central body portion relative to the longitudinal axis in the expanded deployed configuration, and

wherein the wing portion fits within one of the openings in the central body portion of the stent structure in a crimped delivery configuration; and

a valve structure comprising a plurality of leaflets attached to an interior of the stent structure; and

deploying the stented valve prosthesis at an implantation location within the native mitral valve.

18. The method of claim **17**, wherein deploying the stented valve prosthesis comprises positioning the stented valve prosthesis such that the wing portion of the stent structure engages a mitral valve annulus on an atrial side of the native mitral valve, the central body portion of the stent structure is located within the native mitral valve annulus, and the second end of the stented valve prosthesis is located on a ventricular side of the native mitral valve.

19. The method of claim **17**, wherein inserting the delivery system into the body lumen comprises percutaneously advancing the delivery system to the native mitral valve via a catheterization technique.

20. The method of claim **17**, further comprising removing the delivery system from the body lumen after deploying the stented valve prosthesis.

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